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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER
	14

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/125,122	TARRO ET AL.	
	Examiner	Art Unit	
	Bridget E. Bunner	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 September 2000*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15)☒ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
18)☐ Interview Summary (PTO-413) Paper No(s). _____.
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other:

DETAILED ACTION

The examiner and Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Bridget E. Bunner in Group Art Unit 1647.

Continued Prosecution Application

The request filed on 15 September 2000 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/125122 is acceptable and a CPA has been established. An action on the CPA follows.

Status of Application, Amendments and/or Claims

The preliminary amendment of 15 September 2000 (Paper No. 13) has been entered in full. Claims 1-6 have been cancelled. Claims 7-19 are under consideration in the instant application.

Withdrawn Objections and/or Rejections

The objection to claim 5 as set forth in item 4 of the previous Office Action (Paper No. 9, 17 March 2000) is withdrawn in view of the cancelled and newly submitted claims (Paper No. 13, 15 September 2000).

The rejections to claims 1-4 as set forth in items 6 and 8 of the previous Office Action (Paper No. 9, 17 March 2000) are withdrawn in view of the cancelled and newly submitted claims (Paper No. 13, 15 September 2000).

Specification

1. The application papers are objected to under 37 C.F.R. § 1.52(a) because they are not uniformly legible and are not of sufficient quality to permit xerographic reproduction.

2. The disclosure is additionally objected to because of multiple informalities too numerous to catalog. Among these are incomplete, awkward, or nonidiomatic translations, *e.g.*, "high amount of active principle" (page 2, line 9); "posology" (page 4, line 2); "as opposite to" (page 4, line 18); "U/die" (page 6, line 24). There are additionally a number of typographical errors, and British rather than American spellings are employed throughout.

A substitute specification incorporating suitable revisions is required. The substitute specification must be accompanied by a statement that it contains no new matter. *See* 37 C.F.R. § 1.125. However, compliance with this requirement may be deferred pending the identification of allowable subject matter.

Claim Objections

3. Claims 7 and 8 are objected to under 37 C.F.R. § 1.75(b) as being duplicate claims. The claims appear to be identical in scope and content because they differ only with respect to intended uses for the products made by the claimed "uses." The intended uses *per se* are accorded no patentable weight in construing the claims, and they appear to impose no material or functional limitations on the method steps practiced to make a medicament or on the products produced.

One of the duplicate claims should be canceled or otherwise amended to delimit a different scope of the invention. Applicant's attention is also directed to M.P.E.P. § 706.03(k).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 7-8, 11-14 and 17-19 are rejected under 35 U.S.C. § 103(a) as being unpatentable over either one of Cummins, U.S. Patent No. 5,824,300, or Cummins, WO 88/03411.

Each of the Cummins references describes aqueous formulations of human interferon (IFN-) which are suitable for use in the therapeutic methods it describes and claims. *See* '300 at col. 3; '411 at pages 5-6; and the claims of each. Such methods call for delivery to the oropharyngeal mucosae of IFN in solution at dosages preferably ranging from about 0.5 to 1.5 IU per pound per day. '300 at claim 3; '411 at claim 1. For typical patients weighing from about 100 to 225 pounds (*ca.* 45-100 kg), the preferred dosages are thus on the order of 50 to 340 IU IFN-α per day. Among the preferred sources of IFN are buffy coat leukocytes. '300, col. 3, lines 25-35; '311, page 4, liens 2-6. Each of the references teaches that the IFN may be administered once daily or in divided doses. '300 at col. 5, lines 56-61; '311 at the paragraph bridging pages 11-12. Exemplary formulations described by Cummins contain 1-1500 IU of IFN in a dosage volume of one tablespoon (15 ml), or 0.07-100 IU ml^{-1}. '300 at col. 14, lines 1-5; '411 at page 31, first full paragraph. A specific formulation is not described.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to prepare an aqueous solution containing 1-1500 IU of human leukocyte IFN-α in a convenient single-dose delivery volume for oral administration, *e.g.*, 1 tablespoon (15 ml), because Cummins teaches that it is desirable to do so. The concentration range claimed by applicant overlaps the prior art range, and the prior art and the claimed formulations comprise the same active ingredients and are employed in the same manner, *i.e.*, oral delivery in a manner that promotes contact between the IFN solution and the oropharyngeal mucosae. The intended uses recited in the instant claim impose no material or functional limitations on the formulations *per se* or the methods of making them and thus do not patentably define over the prior art formulations.[1] The claimed invention would have been *prima facie* obvious as a whole at the time it was made, especially in the absence of evidence to the contrary.

5. Claims 9-10 and 15-16 are rejected under 35 U.S.C. § 103(a) as being unpatentable over either one of Cummins '300 or '411 as applied to claims 7-8, 11-14 and 17-18 above, further in view of Ratajczak *et al.*, *Arch. Immunol. Ther. Exp.* 41: 237-40 (1993).

The relevant teachings of the Cummins references are as discussed above in connection with the rejections under § 103(a). Neither describes a formulation employing lymphoblastoid hIFN-α.

Ratajczak describes the use of lozenges containing 50 or 100 IU of human lymphoblastoid IFN-α for oropharyngeal delivery in the treatment of hepatitis B infections. *See* the title and page 239, col. 1, first paragraph.

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[1] It is however noted that each of the Cummins references teaches that its formulations are suitable, *inter alia*, for the treatment of viral and neoplastic diseases according to the methods it describes.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to prepare an aqueous formulation of hIFN-α according to Cummins '300 or '411, employing lymphoblastoid IFN as described by Ratajczak in place of the buffy coat leukocyte IFN noted particularly by Cummins, because Ratajczak evidences that lymphoblastoid IFN was readily available at the time of the invention and teaches that it is suitable for the treatment of an exemplary viral disease *via* delivery to the oropharyngeal mucosae. It consequently would have been obvious to the artisan that lymphoblastoid IFN would be the functional equivalent of any of the hIFN-α preparations expressly described by Cummins for use in the methods described in the '300 and '411 references. The claimed invention would have been *prima facie* obvious as a whole at the time it was made, especially in the absence of evidence to the contrary.

Conclusion

6. The art made of record and not relied upon is considered pertinent to applicant's disclosure:

U.S. patent 6,048,843 (Tóth)
EP 1005868 (Grint et al.)

7. All claims are drawn to the same invention claimed in the parent application prior to the filing of this Continued Prosecution Application under 37 CFR 1.53(d) and could have been finally rejected on the grounds and art of record in the next Office action. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing under 37 CFR 1.53(d). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (703) 305-7148. The examiner can normally be reached on 8:30-5:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Elizabeth C. Kunz

Bridget E. Bunner
Art Unit 1647
December 1, 2000